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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,334	12/30/2004	Mitsuru Maeda	47233-0042	8952
55694 7590 01/29/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER MCINTOSH III, TRAVISS C	
			ART UNIT 1623	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/29/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/500,334	MAEDA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,11-15,21 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,11,12,14,15,21 and 26 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The After Final Amendment filed December 22, 2006 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 9, 14-15 and 21 have been amended.

Claim 26 has been added

Claims 2-7, 10, 16-20, and 22-25 have been canceled.

Remarks drawn to rejections of Office Action mailed 7/31/2006 include:

112 2<sup>nd</sup> paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(b) rejection: which have been overcome by applicant's amendments and have been withdrawn.

It is noted that the finality of the previous office action is hereby withdrawn to apply a new ground of rejections as set forth herein.

An action on the merits of claims 1, 8-9, 11-15, 21, and 26 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

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***Claim Rejections - 35 USC § 102***

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al. (US 5,407,812).

Sakai et al. disclose 2-O- $\beta$ -D-glucopyranosyl-L-ascorbic acid, which meets the limitations of claim 1 of the instant application (see column 2, line 23).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 9, 11-12, 14-15, 21, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. as applied above, in view of Kawada et al. (US 4,754,026).

Claim 1 is drawn to a 2-O- $\beta$ -D-glucopyranosyl-L-ascorbic acid compound. Claims 8 and 9 provide the saccharide comprises acetyl groups in the 2', 3', 4', and 6'-positions of the sugar. Claims 11 and 12 are drawn to methods of making the product using a glucosyltransferase. Claims 14-15, 21, and 26 are drawn to various forms of compositions comprising the active agent.

Sakai et al. disclose the non-acetylated compound as set forth supra. Sakai et al. teach to make their compounds using a saccharide-transferring enzyme (see paragraph bridging columns 3 and 4). Sakai et al. teach that an amount of 0.001% or more is acceptable for use of their alpha-derivative (see column 8, lines 33-48). Sakai et al. also teach that their composition may be used in various forms, such as cosmetic, pharmaceutical, or dietary uses (see column 9, lines 49-61). What they do not teach is the acetylated derivatives of claims 8-9, nor methods of using the beta-derivatives as instantly claimed.

Kawada et al. teach that saccharides are protected with acetyl groups at the 2', 3', 4', and 6' positions (see column 2, lines 62-66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to protect the saccharide with the acetyl groups. The use of acetyl groups as protecting agents in saccharide chemistry is very well known. One of skill in the art would have been motivated to protect the compound with the acetyl groups in methods of making the products, as these

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protecting groups are well known in the art, and commonly used in the art. One of skill in the art would have a reasonable expectation of success in using acetyl groups as protecting agents for the saccharide synthesis, as these are well known agents in the art. Moreover, Sakai et al. teach methods of making their compounds using L-ascorbic acid and their  $\alpha$ -glucosyl saccharide and a saccharide-transferring enzyme. As such, it would be obvious to make the  $\beta$ -derivatives as instantly claimed with the methods of making the  $\alpha$ -glucosyl derivatives in the art merely by using a  $\beta$ -derivative as a starting compound instead of the art taught  $\alpha$ -glucosyl compound, as well as using a  $\beta$ -transferase. Moreover, the fact that applicants obtained compositions comprising both 2-O and 6-O derivatives is seen to be inherent within the methods taught. That is, since the methods claimed are seen to be obvious, and the 6-O derivative is produced by the obvious method, the method of making the mixture, as well as the mixture, is also seen to be obvious. It is noted that the Sakai et al. reference is drawn to the use of the alpha-derivative; however, a composition (composition plus carrier) is allowable only if no utility is disclosed for the old compound. See Ex parte Erdmann, 194 USPQ 96. or Ex parte Douros, 163 USPQ 667 (PTO Bd. App. 1968).

### ***Conclusion***

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657.

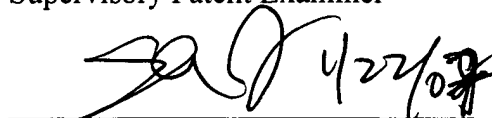
The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh  
January 20, 2007

Shaojia A. Jiang  
Art Unit 1623  
Supervisory Patent Examiner

A handwritten signature in black ink, appearing to read 'SAJ 1/22/07', is written over a horizontal line.